

REMARKS

Claims 1-20 are pending in the present application. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1-9, 12, 13 and 15-17 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,569,106 to Ullman.

Claim 1 recites a protective package for an elongated medical device comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein *a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of elongated medical device*" and "a hydration opening disposed between the first and second ends of the sheath."

In contrast, Ullman describes a medical guide wire containment device consisting of a housing 11 having three individual isolation chambers 13-15 therein. Each chamber includes a funnel 18 extending externally therefrom for receiving a distal end of a guide wire 16. After being inserted into the funnel 18, the distal end follows a fixed spiraling guide 27 to ensure that the guide wire 16 spirals without entanglement. *Ullman*, col. 5, lines 13-17.

In the final rejection, the Examiner states that the Applicants have not considered Fig. 4 of Ullman in response to the rejection. The fixed spiraling guide 27 (what the Examiner equates to the claimed sheath) is shown only in Fig. 4 and was considered, as was the cited disclosure of Ullman. However, applicants respectfully submit that neither the isolation chamber 13 nor the fixed spiraling guide 27 of Ullman is a protective sheath "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1.

Initially it is noted that, although the Examiner stated that Ullman "discloses a structure which meets the definition [of sheath], particularly with respect to the function of a sheath of a blade," (7/19/05 *Office Action*, p. 5) no comparison was made between the parts of the Ullman device and that of a sheath. Specifically, it is respectfully submitted that the term sheath does not encompass all structures which receive an item. That is, a parking garage is not a sheath for a car. Rather a sheath is a "case for a blade...or other instrument *to which it fits closely*." (Webster's Third International Dictionary, 1986).

The Examiner states that the fixed spiraling guide 27 is a sheath as claimed. Ullman states only that the guide 27 "establishes a fixed pathway to ensure the guide wire 16 will spiral in a selected manner without entanglement." *Ullman*, col. 5, lines 14-16. Fig. 4 shows this guide 27 as a coiled wall which will engage only the leading tip and a radially outer side of a wire 16 inserted into the device 10. That this guide 27 is not a sheath is made clear from Fig. 4 which shows that a width of a proximal portion of the passage through which the wire 16 will be inserted is significantly smaller than a width of the passage defined by the guide 27 -- several times smaller. Thus, it is respectfully submitted that it is improper to infer that the space within the guide 27 closely fits the wire 16. In addition to the increased width of this space within the guide 27, it is noted that Ullman provides absolutely no disclosure of the size or shape of this space in a direction perpendicular to the plane of Fig. 4. Furthermore, the guide 27 ends at an open central chamber which leaves the distal portion of the wire 16 completely uncontained. Thus, applicants respectfully submit that the spiraling guide 27 is not a sheath as recited in claim 1.

Secondly, the Examiner maintains that the isolation chamber 13 is suitable to receive an entire guide wire 16 encompassing both its distal and proximal ends. However, it is noted that this suggestion is contrary to the disclosure of Ullman. In fact, Ullman states that "the wire is pushed all the way in [the chamber] until a small amount, such as about 1-2 cm, remains external to the membrane." *Ullman*, col. 2, lines 60-62. The tip 16a is never received by the chamber 13 so that the wire may be easily removed from the chamber 13. The Examiner states

that "the funnel portion [18-20] is suitable to receive the end of the guidewire or catheter entirely within the funnel portion, and yet still allow easy removal of the guidewire or catheter from the package." 7/19/05 *Office Action*, p. 6. The Examiner does not explain how the guidewire would be removed from the isolation chamber 13 if the tip 16a were not external to the chamber 13. It remains unclear how a user would pull the guide wire 16 from the chamber 13 when the tip 16a is located within the chamber 13. However, if the Examiner is implying that, while within the funnel portion, a proximal end of the guide wire 16 could still be grasped for removal therefrom, this indicates clearly that this funnel portion also does not constitute a sheath. That is, it clearly does not fit the item inserted therein closely. As in the case of a sheath for a blade, such increased width allowing access is the very thing a sheath is designed to prevent. Thus, it is respectfully submitted that neither the chamber 13, the funnel portion thereof or the guide 27 (or any combination of these elements) constitutes a sheath as recited in claim 1.

Applicants respectfully submit therefore that claim 1 is allowable. Because claims 2-9, 12 and 13 depend from, and, therefore include all of the limitations of claim 1, these claims are also allowable.

Claim 15 recites a catheter kit comprising "a catheter having a shaped distal tip" and "a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter" in conjunction with "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to received a proximal end of the catheter" and "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends."

The Examiner states that the fixed spiraling guide 27 of Ullman is a tubular enclosure as claimed. As noted above, Ullman provides absolutely no disclosure of the size or shape of the space within the guide 27. That is, there is no suggestion that the space might be a

tube or that a diameter/width of the space corresponds to an outer diameter of the guide wire 16. Thus, applicants respectfully submit that the spiraling guide 27 is not a tubular enclosure as recited in claim 15.

Additionally, Ullman does not disclose or suggest "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to received a proximal end of the catheter," as recited in claim 15. The tip 16a of the guide wire 16 remains external to the chamber 13, and, as such, is never received therein.

Further, Ullman does not disclose or suggest a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15. In support of the rejection of claim 15, the Examiner reads features of Ullman from the drawings, such as "both ends are below the port 30" and "even if the first end 26 were higher than the port 30, which it is not." Initially, it respectfully submitted that Ullman does not disclose or suggest these features recited by the Examiner. Further, patent drawings are not to scale and any inferences made by the Examiner regarding dimensions and/or structural features of the device without supporting disclosure are improper. Applicants also respectfully submit that fluid delivered to the isolation chamber 13 via the filling port 30 is never directed toward the entry port 21. Ullman states that the fluid fills the isolation chamber 13, but never discloses or suggests that any fluid would be directed toward the entry port 21.

Therefore, Applicants respectfully submit that claim 15 is allowable. Because claims 16 and 17 depend from, and, therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claims 1-7 and 9-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,588,588 to Samuels.

Applicants respectfully submit that Samuels neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath." Samuels describes a hoop packaging tube 40 consisting of a leading opening 44 and a trailing opening 48. An adapter 10 connecting the openings 44 and 48 includes a funnel 24 for receiving one or more guidewires 60. A guidewire 60 is inserted into the tube 40 via the adapter 10, winding wind around the tube 40 until the guidewire 60 has been fully inserted therein. At no point does Samuels teach or suggest that the adapter 10 is suitable for receiving fluid or that fluid inserted thereinto would hydrate the tube 40. In fact, Samuels states that "[a]fter the guidewire is reinserted into the packaging tube, the adapter 10 may be removed...and the bridge connector may be reinserted to close the loop of the packaging tube." *Samuels*, col. 3, lines 40-44.

The Examiner maintains that a port 30 on the adapter 10 is usable as a hydration opening, and that further evidence of this use is provided in U.S. Patent No. 6,375,006 to Samuels ("'006 patent"). The '006 patent describes a flexible pipe 12 having a sealed end 14 and an open end 16 with a nozzle 20 attached thereto. It is never disclosed or suggest that the nozzle 20 is "disposed between the first and second ends" of the pipe 12. In fact, this would be contrary to the disclosure of the '006 patent which repeatedly describes the apparatus as having one open end and one sealed end, which teaches away from the present invention. Further, the combination of these references would be improper, because Samuels teaches two open ends, whereas the '006 patent teaches only one open end. Thus, it is respectfully submitted that neither Samuels nor the '006 patent discloses or suggests "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Therefore, because claims 2-7 and 9-14 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 8 and 15-20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Samuels in view of Ullman. The Examiner states that Samuels discloses the invention substantially as claimed but does not disclose use with a catheter.

It is respectfully submitted that Ullman does not cure the above-described deficiencies of Samuels. Thus, because claim 8 depends from, and, therefore includes all of the limitations of claim 1, it is respectfully submitted that this claim is also allowable. With regard to claim 15, neither Samuels nor Ullman discloses "the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends." Specifically, Samuels does not disclose or suggest that the adapter 10 or the tube 40 are suitable for hydration. As noted above, Ullman does not teach that saline solution inserted into the chamber 13 via the filling port 30 is directed in any manner toward the two ends of the chamber 13. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses or suggests, "the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15. Because claims 16-20 depend from, and, therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claims 1, 3, 6-9, 12, 13, 15, 16 and 19 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,861,395 to Taniguchi.

In contrast to the present invention, Taniguchi describes a catheter assembly 10 consisting of a body 12 and a protective bag 70 extending distally therefrom. A distal end of the protective bag 70 is freely movable and does not attach to the body 12 in any manner. The Examiner states that Taniguchi shows a reservoir 31 disposed between a proximal end of the body 12 and a distal end of the bag 70. Initially, it should be noted that Taniguchi does not provide any disclosure with regard to reference numeral 31 and does not include any mention of "a reservoir." Thus, it is unclear what feature numeral 31 is drawn to and no function is described for this element. Taniguchi does provide, however, that a lubricant bladder 32 is punctured by a spike 33 when a cover 30 enclosing the bladder 32 is depressed. The bladder 32 empties onto a proximal end of a catheter 68. It is respectfully submitted that a one-time covering of the proximal end of the catheter 68 in lubricant cannot be equated to the "hydration opening," as recited in claim 1.

Furthermore, the Examiner suggests that the body 12 combined with the bag 70 make up a structure equatable with the recited "protective sheath." Applicants respectfully submit that the body 12 and the bag 70 are separate structures, neither of which can be considered a protective sheath, as recited in claim 1. For example, the bag 70 does not include a hydration opening between proximal and distal ends thereof. And, the body 12 does not include "a first end...adapted to receive a distal end of the elongated medical device and a second end...adapted to receive a proximal end of elongated medical device." Thus, it is respectfully submitted that Taniguchi does not disclose or suggest "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1, or "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof," as recited in claim 15. Because claims 3, 6-9, 12 and 13 depend from, and therefore include all of the limitations of claim 1, and, because claims 16 and 19 depend from, and, therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claim 4 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Taniguchi in view of U.S. Patent No. 4,805,611 to Hodgkins. The Examiner states that Taniguchi discloses the invention substantially as claimed but fails to teach a luer or adapter capable of receiving a syringe. Applicants respectfully submit that Hodgkins does not cure the above-described deficiencies of Taniguchi. Thus, because claim 4 depends from, and, therefore includes all of the limitations of claim 1, it is respectfully submitted that this claims is also allowable.

Claims 1, 4, 7 and 9-11 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,597,264 to Laak.

Laak describes a leaching field consisting of a manifold for receiving effluent from a septic tank and directing the effluent through parallel outlets in the manifold. In support of the rejection, the Examiner states that the leaching field in Laak could hold an elongate medical device, and as such, anticipates claim 1 of the present invention. At no point does Laak disclose or suggest that the manifold includes "a protective sheath including a lumen sized to

receive a body of *the elongated medical device*,” as recited in claim 1. In fact, the manifold receives a continuous flow of effluent therethrough from a septic tank. As such, Laak never suggests that an elongated medical device is received in the manifold and subjected to contact with the flow of effluent. Furthermore, it is respectfully submitted that one of skill in the art would have been initiated to employ the teaching of Laak as described by the Examiner in view of the goals of sterility and prevention of infection/contamination, which are common in the medical field in addition to the numerous other differences in size, materials, etc. which separate these fields.

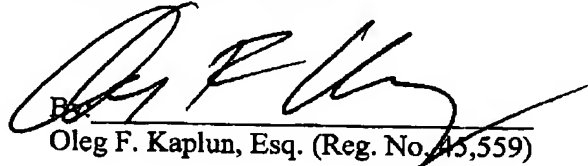
Therefore, Applicants respectfully submit that Laak neither discloses nor suggests “a protective sheath including a lumen sized to receive a body of *the elongated medical device*,” as recited in claim 1. Because claims 4, 7 and 9-11 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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